Application Number 10/767,545
Response to Office Action mailed January 28, 2008

## REMARKS

This communication is responsive to the Office Action dated January 28, 2008.
Applicant has not amended the claims by way of this communication. Claims 19-54 remain
pending.

### Claim Rejection under 35 U.S.C. § 102/103

In the Office Action, the Examiner rejected claims 19-23, 32-41, 50-54 under 35 U.S.C. §
102(b) as anticipated by Snell (US 5,716,382), or, in the alternative, under 35 U.S.C. § 103(a) as
obvious over Snell. Applicant submits that the present claims are distinguishable from the Snell
reference, and respectfully traverses this rejection. Snell does not disclose each and every feature
of the claimed invention, as required by 35 U.S.C. 102(b), nor does it provide any motivation to
one of ordinary skill in the art to include the undisclosed features, as required by 35 U.S.C.
103(a).

Snell describes a decision support system for use by physicians in optimizing the
parameters of an implantable cardiac device. The system is comprised of a rule engine unit, a set
of rules, patient and device databases, and interfaces for interacting with the operator.[1]
According to Snell, the operator engages with the system in a question and answer session, from
which the system learns aspects of the patient's condition.[2] The answers provided by the
operator are gathered from telemetric readings or from a patient/device database.[3] Based on that
information, the system recommends an appropriate operating configuration for the implantable
device, or provides a list of recommendations from which the physician can choose.[4]

In contrast to Snell, claim 19 is recites a device comprising a processor programmed to
select a first parameter configuration for a neurostimulator, receive an indication of observed
efficacy of the first parameter configuration, select a branch of a decision tree based on the
indication of observed efficacy of the first parameter configuration and a position of the first
parameter configuration within the decision tree, wherein the decision tree defines a hierarchy of
possible parameter configurations, and select a second parameter configuration for the

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[1] Snell at col. 3, lines 35-49.
[2] Snell at col. 3, lines 41-43.
[3] Snell at col. 7, line 17.
[4] Snell at col. 3, lines 44-48.

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neurostimulator based on the selected branch of the decision tree. Such features may, for example, permit an operator to refine an initial configuration, using the indications of the efficacy of the initial configuration, to a different configuration based on the appropriate branch of the decision tree. The Snell reference discloses neither the use of indications of observed efficacy of one (e.g., a current) parameter configuration to select a next parameter configuration, the use of a decision tree that defines a hierarchy of possible parameter configurations, nor the selection of a different parameter configuration on the basis of such indications and the present position within the decision tree.

The Examiner argues that FIGS. 4 and 5 of Snell disclose the use of observations of efficacy as a result of pacing. However, the examples cited by the Examiner relate to the patient's underlying condition and not to the effects of a particular (e.g., the current) pacing mode. In particular, the Examiner cites blocks 2, 3, 5, and 6 of FIG. 5. Block 2 asks the operator whether the patient's need for a pacemaker will be infrequent,[5] while Block 3 asks whether pacing is needed as a result of neuroregulatory abnormality.[6] These two questions relate to the patient's underlying condition;[7] they are not answered by observing the effects of pacing, much less pacing in a current mode. Block 5 asks whether there is evidence of atrial fibrillation,[8] and block 6 asks if ventricular rate increases with physiological stimulation.[9] These two questions are also answered on the basis of the patient's underlying condition and not by observing the effects of pacing, much less pacing in a current mode.[10]

In the Snell system the selection of a next parameter configuration is not the result of observations of the efficacy of pacing in a previous or current parameter configuration. Rather, the operator inputs information based on clinical observation of conditions unrelated to pacing. Snell therefore cannot anticipate the requirement of claim 19 of a device to "receive an indication of observed efficacy of the first parameter configuration." With regard to the Examiner's obviousness rejection, the Examiner did not explain why one of ordinary skill in the art would have been motivated to modify the Snell system so that it would receive an indication of

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[5] Snell, FIG. 5.
[6] Id.
[7] Snell at col. 10, lines 40-51.
[8] Id.
[9] Id.
[10] Snell at col. 11, lines 50-61.

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observed efficacy. Since the decision tree within the Snell system does not consider the effects of the pacing, such indications would have had no value to its operation. As a result, such motivation to modify does not exist within Snell or within the knowledge of one of ordinary skill. Therefore claim 19 is not obvious over Snell.

The Examiner stated that, in the Snell system, as a "result of its efficacy [and] the location of the first parameter configuration [, the device] selects a second parameter configuration." The Applicant has already shown that efficacy is not a component of the Snell system. In addition, the Snell system does not select subsequent parameter configurations based on the location of the position of the current configuration within a decision tree composed of a hierarchy of configurations. To the contrary, the various parameter recommendations in Snell, as illustrated in FIGS. 5, 6, and 7, are all *leaves* of the decision tree. That is, once a recommendation is reached through use of the decision tree, there are no further branches of decisions to take and the tree traversal process is complete. Snell refers to these leaves/configurations as "tips" of the branches of the tree.[11] There are "62 such tips corresponding to 62 different recommendations for the adjustable pacing parameter."[12] Because the configurations in Snell are the end result of the decision-making process, that reference cannot anticipate or make obvious the limitation of claim 19 that requires "select[ing] a branch of a decision tree based on the indication of observed efficacy and position of the first parameter configuration within the decision tree, wherein the decision tree defines a hierarchy of possible parameter configurations."

While the above arguments were made with respect to claim 19, Applicant's independent claim 37 sets forth substantially similar limitations as that of claim 19. As a result, independent claim 37 benefits from the above arguments made with respect to claim 19, and Applicant requests prompt withdrawal of its rejection for similar reasons. Additionally, those claims 19-23, 32-41, 50-54 that depend on independent claims 19 and 37 also benefit from the above arguments made with respect to claim 19, and Applicant also requests withdrawal of the rejection set forth against these dependent claims.

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[11] Snell at col. 9, line 9.
[12] Snell at col. 9, lines 10-12.

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For at least these reasons, the Examiner has failed to establish a prima facie case for either anticipation under 35 U.S.C. 102(b), or for obviousness under 35 U.S.C. 103(a), of Applicant's claims 19-23, 32-41, 50-54. Withdrawal of this rejection is requested.

## Claim Rejection under 35 U.S.C. § 103

The Examiner also rejected claims 19-54 under 35 U.S.C. § 103(a) as being unpatentable over Kroll et al. (US 7,123,961) in view of Snell (US 5,716,382). Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Kroll fails to disclose or suggest a device comprising a processor programmed to select a first parameter configuration for a neurostimulator, receive an indication of observed efficacy of the first parameter configuration, select a branch of a decision tree based on the indication of observed efficacy and a position of the first parameter within the decision tree, *wherein the decision tree defines a hierarchy of possible parameter configurations*, and select a second parameter configuration for the neurostimulator based on the selected branch of the decision tree, as recited in Applicant's independent claim 19. The Examiner correctly noted that the present application differs from Kroll, at a minimum, in that it "recite[s] a hierarchy [] of electrode configurations to form a decision tree to determine the optimum settings."

However, the Applicant disagrees with the Examiner's statement that to "have used such a well known method for selecting configurations in a known manner would have been obvious in view of Snell." As already argued above, Snell does not disclose or suggest the use of a decision tree defined by a hierarchy of possible parameter configurations. The configurations in Snell are found only at the leaves of the decision tree. Once they are reached, the tree-traversal process is complete. In contrast to Applicant's claim 19, therefore, the configuration in Snell cannot be used in conjunction with indications of observed efficacy in order to select the next parameter configuration by traversing the tree. Consequently, Snell does not cure the deficiencies of Kroll, as suggested by the Examiner.

While the above arguments were made with respect to claim 19, Applicant's independent claim 37 sets forth substantially similar limitations as that of claim 19. As a result, independent

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claim 37 benefits from the above arguments made with respect to claim 19, and Applicant requests prompt withdrawal of its rejection for similar reasons. Additionally, those claims 19-54 that depend on independent claims 19 and 37 also benefit from the above arguments made with respect to claim 19, and Applicant also requests withdrawal of the rejection set forth against these dependent claims.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 19-54 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.
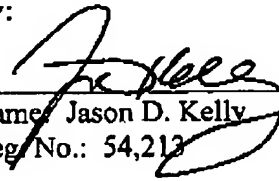
## CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

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